



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,372	02/26/2004	Gottfried Mueller	HOE-803	5135

20028 7590 03/29/2007
Lipsitz & McAllister, LLC
755 MAIN STREET
MONROE, CT 06468

EXAMINER

DOWE, KATHERINE MARIE

ART UNIT	PAPER NUMBER
----------	--------------

3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/789,372

Applicant(s)

MUELLER ET AL.

Examiner

Katherine M. Dowe

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-11,13-15,17-32,34,35,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-11,13-15,17-32,34,35,37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following is a complete response to the amendment filed 2/5/2007.

Examiner acknowledges the amended claims (1, 5, 7, 10, 11, 13, 17-19, 23-24, 27, 30-32, 34-35, and 37-38) and cancelled claims (2, 3, 12, 16, 33, and 36). Currently, claims 1, 4-11, 13-15, 17-32, 34, 35, 37, and 38 are pending.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 31, 32, 34, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by King et al. (US 3,874,388). King et al. disclose a closure device (see Fig 1C) comprising a plurality of wings (81) with bearing areas (82) and a base part (84). Furthermore, the wings are held by hinge joints (Fig 4, element 86') that allow the wings to be movably attached to the base part (col 6, lines 39-41). King et al. disclose an applicator device for the said closure device comprising a longitudinally displaceable positioning element (Figs 9C-9D, element 2) that transfers the closure device from the flapped-in position to the flapped-out position. The positioning element comprises bearing areas for the wings for swiveling the wings out (col 9, lines 35-37). The applicator device further comprises a holding mandrel to hold and position the closure device (Figs 9B-9E, element 3), wherein the positioning element (2) surrounds the holding mandrel (3) at least partially (col 7, lines 59-60). The holding mandrel can be displaced longitudinally within the positioning element to guide the closure device (Figs

9B-9E; col 9, lines 30-32). Finally, King et al. disclose the positioning element (Fig 9c, element 2) provides a centering means for the holding mandrel (3) by acting as a guide through the outer trocar sheath, or catheter (1).

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 4-11, 13-15, 17-20, 23-26, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. (US 3,874,388) in view of Redmond et al. (US 6,613,070). Regarding claims 1 and 6, King et al. disclose the device substantially as claimed including a closure device (see Fig 1C) comprising a plurality of wings (81) with bearing areas (82) and a base part (84). The wings are held by hinge joints (Fig 4, element 86') that allow the wings to be movably attached to the base part (col 6, lines 39-41). The joints (Fig 2B, element 86) are seated on the upper side of the base part facing the tissue (right end of element 84a). The wings are hinged to the base part such that in the flapped-in position, the wings do not protrude laterally over base part (Fig 2A and Fig 2B) to ensure the wings do not occupy any additional space within the trocar sheath, or catheter (col 7, lines 18-20).

However, King et al. does not disclose the joints are film hinges or that the wings are integrally held on the base part. Redmond discloses a vascular sealant delivery device incorporating an articulating foot (Figs 18A and 18B, element 208) that must be sufficiently flexible to shift between its non-deployed, or flapped-in, position (Fig 18B) to

Art Unit: 3734

its deployed, or flapped-out, position (Fig 18A). Redmond teaches a variety of mechanisms for an articulated, or pivotable, attachment of the foot to the shaft (206) that may be utilized, including a living, or film, hinge (col 11, lines 25-32). Furthermore, by definition a living hinge works by weakening a region in the material where pivotable movement is desired (col 11, line 30) and thus the two hinged segments must be integrally formed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the surgical closure device of King et al. to form the wings integrally on the base part and incorporate film hinges. Thus the joint is one integral piece making the joint less prone to failure as well as easier and more economical to manufacture.

Regarding claims 4 and 14, King et al. disclose the wing joints (see Fig 2B, element 86) are oriented at a right angle to the base part (84a). Thus, the wings are oriented at a right angle to the central axis of the base part when the device is in the flapped-out position (See Fig 9E, where element 3 is along the central axis of the base part and elements 83 form a perpendicular axis). Furthermore, King et al. disclose a ring element (Fig 2B, element 87) to prevent the wings from opening past 90 degrees (col 6, lines 42-44).

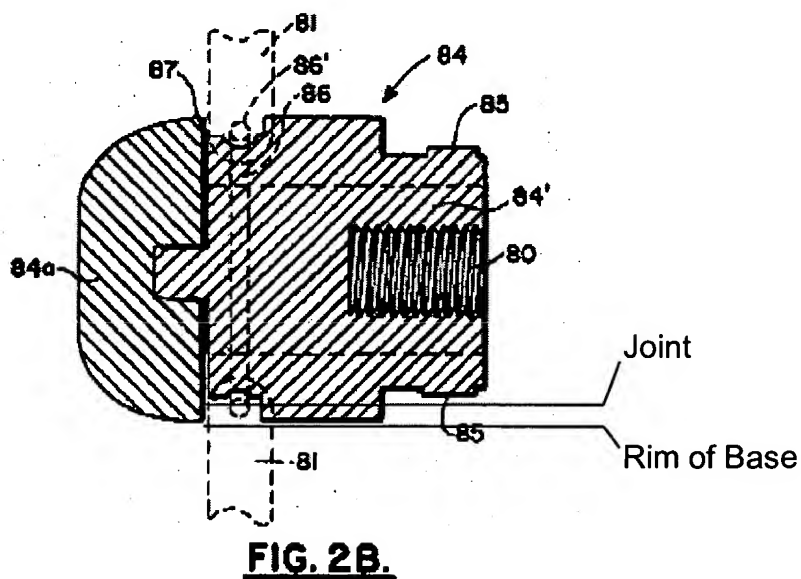
Regarding claim 5, King et al. disclose the wing joints lie parallel to tangents to an outer circumference of the base part (see Fig 9B – 9D). Thus, the wings emanate out from the central axis of the base part in at least a generally perpendicular, radial direction when in the flapped-out position and in at least a generally parallel, axial direction when in the flapped-in position (col 12, lines 28-33).

Regarding claims 7 and 11, King et al. disclose the wings (col 6, line 21) and the base part (col 6, line 34-35) in an area outside the associated joint are made of stainless steel and are, therefore, of substantially rigid design.

Regarding claims 8 - 10, King et al. disclose the wings hold bearing elements spanned between adjacent wings (Fig 10B, element 82; col 12, line 41). The bearing elements are made of bendable material (col 6, lines 49-55) and are folded when the closure device is in the flapped in position (Fig 2A, element 82).

Regarding claim 13, King et al. disclose the wings form and/or hold bearing areas on the tissue when the device is flapped out (Fig 10B, elements 81 and 82).

Regarding claim 15, King et al. disclose the joints are set back from a circumferential rim of the base part (see Fig 2B below).



Regarding claims 17-19, King et al. disclose at least two wings (Fig 2A, element 81), wherein the wings are diametrically disposed and arranged around the

Art Unit: 3734

circumference of the base part (see arrangement of grooves in the base part adapted to fit the wings - Fig 2C, element 89).

Regarding claim 20, King et al. disclose the base part has a round outer cross section (see Fig 2C).

Regarding claim 23, King et al. disclose the wings may extend at an incline to the base part when in the flapped-in position (Fig 2A, element 82). King et al. disclose the wings should be at least generally parallel to the central axis of the base part, not completely straight (col 12, lines 28-33).

Regarding claims 24-26, King et al. disclose a ring-shaped element (Fig 2B, element 87) on the base part (84) that provides a bearing surface to prevent the wings from opening past 90 degrees (col 6, lines 42-44). Thus, the base provides a bearing area to inhibit swiveling of the wings beyond a bearing position. The wings comprise a support for placement against the associated bearing areas (Fig 2B, distal end of wing 81).

Regarding claims 28-30, King et al. disclose a coupling on the base part for a holding mandrel (Fig 2A, element 3). The coupling includes a central threaded orifice on the proximal end of the base part (Fig 2B, element 80) that mates with the threaded end of the holding mandrel, or guide wire (Fig 5, element 31). King et al. disclose the base part (Fig 2B, element 84) has a holding element (84') and a ring element (87), wherein the ring element prevents the wings from opening beyond 90 degrees (col 6, lines 41-42). Furthermore, the ring element is held on the holding element by a snap closure, wherein the proximal end of the base (84a) fits over the protrusion of the distal

Art Unit: 3734

end of the holding element (84') with a close tolerance thereby sandwiching the ring element (87).

6. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. (US 3,874,388) and Redmond et al. (US 6,613,070), as applied to claim 1 above, in view of Himpens et al. (US 5,397,331). King et al. disclose the device substantially as claimed including a closure device (see Fig 1C) comprising a plurality of wings (81) with bearing areas (82) and a base part (84). The wings are held by hinge joints (Fig 4, element 86') that allow the wings to be movably attached to the base part (col 6, lines 39-41). The joints (Fig 2B, element 86) are seated on the upper side of the base part facing the tissue (right end of element 84a). The wings are hinged to the base part such that in the flapped-in position, the wings do not protrude laterally over base part (Fig 2A and Fig 2B) to ensure the wings do not occupy any additional space within the trocar sheath, or catheter (col 7, lines 18-20).

However, King et al. does not disclose the joints are film hinges or that the wings are integrally held on the base part. Redmond discloses a vascular sealant delivery device incorporating an articulating foot (Figs 18A and 18B, element 208) that must be sufficiently flexible to shift between its non-deployed, or flapped-in, position (Fig 18B) to its deployed, or flapped-out, position (Fig 18A). Redmond teaches a variety of mechanisms for an articulated, or pivotable, attachment of the foot to the shaft (206) that may be utilized, including a living, or film, hinge (col 11, lines 25-32). Furthermore, by definition a living hinge works by weakening a region in the material where pivotable

Art Unit: 3734

movement is desired (col 11, line 30) and thus the two hinged segments must be integrally formed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the surgical closure device of King et al. to form the wings integrally on the base part and incorporate film hinges. Thus the joint is one integral piece making the joint less prone to failure as well as easier and more economical to manufacture.

Furthermore, King et al. disclose the closure device is secured to the tissue by anchoring methods utilizing small projections or barbs (col 6, lines 21-24) and do not disclose securing the closure device to the tissue with suturing methods. Himpens et al. disclose a similar closure device that is secured to the surrounding tissue by suturing means. The base part (Fig 4, element 16) has a pin (18) through which the suture (19) passes and by means of which the suture is held. Himpens et al. teaches the suture is used to secure the closure device in its proper position and is threaded through the holding mandrel to enable simple and quick handling of the device (col 2, lines 56-60). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the securing mechanism of the surgical closure device of King et al. to incorporate sutures and thread the suture through the holding mandrel for easy insertion. Thus, the closure device will be more securely attached to the tissue surrounding the opening.

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. (US 3,874,388) and Redmond et al. (US 6,613,070), as applied to claim 1 above, in

Art Unit: 3734

view of Rousseau (US 6,616,685). King et al. disclose the device substantially as claimed including a closure device (see Fig 1C) comprising a plurality of wings (81) with bearing areas (82) and a base part (84). The wings are held by hinge joints (Fig 4, element 86') that allow the wings to be movably attached to the base part (col 6, lines 39-41). The joints (Fig 2B, element 86) are seated on the upper side of the base part facing the tissue (right end of element 84a). The wings are hinged to the base part such that in the flapped-in position, the wings do not protrude laterally over base part (Fig 2A and Fig 2B) to ensure the wings do not occupy any additional space within the trocar sheath, or catheter (col 7, lines 18-20).

However, King et al. does not disclose the joints are film hinges or that the wings are integrally held on the base part. Redmond discloses a vascular sealant delivery device incorporating an articulating foot (Figs 18A and 18B, element 208) that must be sufficiently flexible to shift between its non-deployed, or flapped-in, position (Fig 18B) to its deployed, or flapped-out, position (Fig 18A). Redmond teaches a variety of mechanisms for an articulated, or pivotable, attachment of the foot to the shaft (206) that may be utilized, including a living, or film, hinge (col 11, lines 25-32). Furthermore, by definition a living hinge works by weakening a region in the material where pivotable movement is desired (col 11, line 30) and thus the two hinged segments must be integrally formed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the surgical closure device of King et al. to form the wings integrally on the base part and incorporate film hinges. Thus the

Art Unit: 3734

joint is one integral piece making the joint less prone to failure as well as easier and more economical to manufacture.

Furthermore, King et al. do not disclose the wings increase in width away from the base part. Rousseau discloses a similar closure device comprising a plurality of petal shaped wings, which increase in width away from the center base part (Fig 2, element 12; col 2, lines 17-18). Rousseau teaches the wing design allows for spiral overlapping of the wings and thus the closure device is able to form a flat disc and come in direct contact with the tissue defect (col 1, lines 46-48). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the wings of the surgical closure device of King et al. such that the width of the wings increased away from the base part.

8. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. (US 3,874,388), as applied to claim 31 above, in view of Himpens et al. (US 5,397,331). King et al. disclose a closure device and applicator device substantially as claimed as shown above; however they disclose the closure device is secured to the tissue by anchoring methods utilizing small projections or barbs (col 6, lines 21-24) and do not disclose securing the closure device to the tissue with suturing methods.

Himpens et al. disclose a similar closure device that is secured to the surrounding tissue by suturing means. The base part (Fig 4, element 16) has a pin (18) through which the suture (19) passes and by means of which the suture is held. Himpens et al. teaches the suture is used to secure the closure device in its proper position and is threaded

Art Unit: 3734

through the holding mandrel to enable simple and quick handling of the device (col 2, lines 56-60). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the securing mechanism of the surgical closure device of King et al. to incorporate sutures and thread the suture through the holding mandrel for easy insertion. Thus, the closure device will be more securely attached to the tissue surrounding the opening.

9. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. (US 3,874,388), as applied to claim 31 above, in view of Shichman et al. (US 6,197,041). King et al. disclose a closure device and applicator device substantially as claimed as shown above. However, they do not disclose a reducing sleeve is provided to position the positioning element. Shichman discloses a similar trocar assembly that includes a reducing sleeve that surrounds the insertable device (Fig 2B, element 130). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the applicator device of the surgical closure device of King et al. to incorporate a reducing sleeve to create a tight fit for the insertable device and prevent unwanted swiveling.

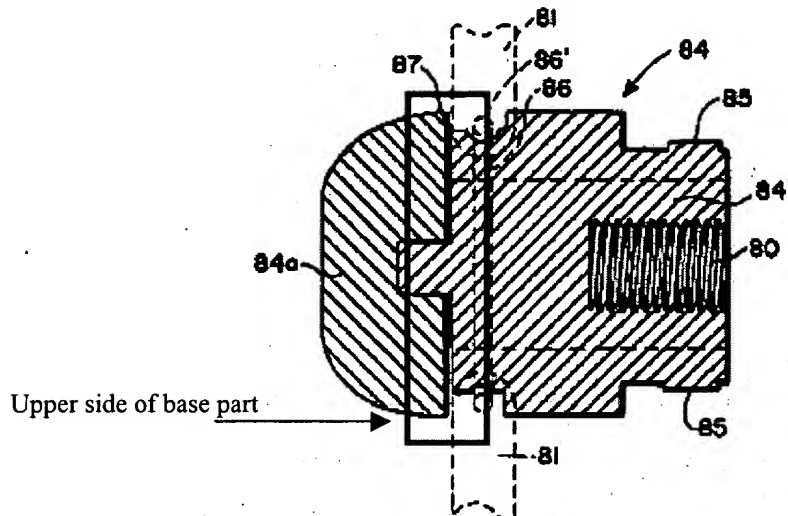
Response to Arguments

10. Applicant's arguments filed 2/5/2007 with respect to claim 3 have been fully considered but they are not persuasive. In response to applicant's argument that Redmond is nonanalogous art, it has been held that a prior art reference must either be

Art Unit: 3734

in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the art is in the medical device field and the reference is used to teach a common engineering concept of using film hinge, or active hinge. As shown in the above rejection, King discloses the invention substantially as claimed including a closure device having a plurality of wings hingedly attached to the base part, however he does not disclose the hinge is a film hinge but rather uses a pin to join to the two pieces together such that the wing may swivel with respect to the base. Thus, since it is commonly known in the art to use a film hinge in place of the hinge joint taught by King, it would have been obvious to one of ordinary skill in the art to use the teaching of Redmond to modify the device of King as shown above.

11. Applicant's arguments filed 2/5/2007 with respect to cancelled claim 16, of which subject matter is now included in claim 1, have been fully considered but they are not persuasive. Applicant argues that King does not disclose the joints are seated on an upper side of the base part, where the upper side of the base part faces the tissue when bearing areas bear on the tissue. As stated in the rejection, the upper side of the base part in King's invention is defined as the right portion of element 84a as shown below:

**FIG. 2B.**

Thus, as can be seen in the picture, the joints formed by hinge holes 86' such that the wings (81) may swivel between a flapped-in position and flapped out position. As shown in Fig 2A, the wings are approaching a flapped-in position, but they are capable of swiveling further in toward mandrel (3) such that they do not protrude laterally over the base part in the flapped-in position.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the *entire* base part does not protrude into the tissue opening) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The upper side of the base part, as defined in King above, does not protrude into the tissue opening as seen in Figs 9E and 9F.

Art Unit: 3734

12. Applicant's arguments filed 2/5/2007 with respect to claim 31 have been fully considered but they are not persuasive. Applicant argues obturator wire 3 of King, which is defined as the mandrel claimed by Applicant, cannot possibly navigate a closure device for positioning it. Applicant's attention is drawn to King col 9, lines 30-34: "By manipulating the obturator wire 3, the distal hub 84 carrying the collapsed left umbrella 8 is advanced beyond the outer, thin wall catheter 1 into the left atrium". Thus, the obturator wire, or mandrel, is capable of navigating and positioning the closure device.

Applicant further argues King does not disclose that a positioning element provides a centering means for holding a mandrel inhibiting relative transverse movability. Although applicant asserts Fig 9C shows the mandrel 3 is not centered within the positioning element 2, Examiner disagrees; please refer to the figure. The positioning element, referred to as an inner catheter by King, surrounds the mandrel 3 such that the mandrel may not move transversely significantly due to its relatively small inner diameter compared to the mandrel. In contrast, the trocar sheath has a much greater inner diameter, which would allow some transverse movability. As seen in Fig 9E, by using and manipulating the mandrel and positioning device properly, the closure device is centered over the tissue opening.

Finally, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., capable of inserting, navigating, positioning and unfolding a closure device without any optical adjusting aids) are not recited in the rejected claim(s).

Art Unit: 3734

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571)272-4959. The fax phone

Art Unit: 3734

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

kmd
March 22, 2007


MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER